UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MARK A. CORBAN, individually and on behalf of all others similarly situated,	*	
Plaintiff,	*	
v.	*	Civil Action No. 14-cv-10201-IT
SAREPTA THERAPEUTICS, INC., CHRIS GARABEDIAN, SANDY MAHATME, and ED KAYE,	*	
Defendants.	*	

MEMORANDUM & ORDER

April 21, 2016

TALWANI, D.J.

Presently before the court is Lead Plaintiffs' Motion for Relief from Judgment Pursuant to Fed. R. Civ. P. 60(b)(2) [#103]. For the following reasons, Plaintiffs' motion is DENIED.

I. Background

This putative federal securities class action was brought under § 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and Rule 10b-5, 17 C.F.R. § 240.10b-5. Plaintiffs' allegations centered on allegedly false or misleading statements issued July 24, 2013 through November 11, 2013 (the "Class Period"), regarding potential FDA approval of eteplirsen, Defendant Sarepta Therapeutics, Inc.'s ("Sarepta" or "the company") lead drug candidate for the treatment of Duchenne Muscular Dystrophy. Consolidated Class Action Complaint [#39] ("Complaint").

On March 31, 2015, the court allowed Defendants' Motion to Dismiss [#42] Plaintiffs' Amended Complaint for failing to allege any actionable misstatements or omissions. See Mem. & Order [#77]. The court concluded that Plaintiffs' allegations regarding feedback the company

had received from the FDA fell short because (1) Defendants' statements regarding the FDA's July 2013 feedback had been adequately qualified by disclosures that the FDA had requested additional information "related to dystrophin quantification and methodology" and that the FDA might determine that "substantial additional data" would be required for approval; (2) Plaintiffs' allegations failed to establish that, to the extent concerns were previously conveyed to the company, this occurred before the challenged statements were made or that those concerns were sufficiently strong as to require disclosure; and (3) Defendants were not under a duty to disclose all of the specific information Plaintiffs sought. Id. at 15-18. Because the court found Plaintiffs had not met their pleading burden under the Private Securities Litigation Reform Act ("PSLRA") of identifying a materially false or misleading statement or omission, the court dismissed the Complaint. The court did not reach Defendants' further argument that Plaintiffs had failed to meet their burden of alleging scienter with particularity.

Plaintiffs thereafter moved for leave to file an amended complaint. Plaintiffs' Proposed Amended Consolidated Complaint [#81-2] ("Proposed Amended Complaint") alleged that statements contained in press releases issued by Sarepta on April 14, 2014 and October 27, 2014, and a statement issued by the FDA on October 30, 2014, demonstrated with the requisite particularity that the FDA had indeed expressed grave concerns to the company prior to the July 2013 meeting.

The court again rejected Plaintiffs' arguments. See Order [#96]. While the court agreed that the FDA's concerns and demands were of such a nature as to require disclosure if Defendants had been aware of them, the court found the new allegations still failed to demonstrate that the FDA had formulated its concerns and demands prior to Defendants making the challenged statements and that Defendants were aware of those concerns when making the

challenged statements. Id. at 2-4. Accordingly, the court denied Plaintiffs' motion for leave to amend, and again declined to reach whether Plaintiffs had adequately alleged scienter under the PSLRA.

Plaintiffs appealed from this court's orders to the First Circuit. While that appeal was pending and before briefing had begun, the FDA released a briefing document on January 15, 2016, in preparation for its upcoming meeting with Sarepta regarding the New Drug Application ("NDA") for eteplirsen. See Pls.' Mem. Law Supp. Mot. Relief J. Ex. 3 [#104-3] [hereinafter "FDA Briefing Document"]. On January 27, 2016, Plaintiffs filed a Motion for Relief from Judgment Pursuant to Fed R. Civ. P. 60(b)(2) [#103], seeking remand of the pending appeal and leave to file a Proposed Third Amended Complaint [#104-1] that makes new allegations based on the FDA Briefing Document.

Plaintiffs contend that the FDA Briefing Document "presents clear and previously unavailable evidence showing that, prior to the Class Period, the FDA expressed material concerns to Sarepta and made many requests for additional data about Sarepta's eteplirsen trial that were undisclosed during the Class Period." Pls.' Mem. Law Supp. Mot. Relief J 2 [#104]. Plaintiffs specifically point to six statements in the Clinical Team Leader's Memorandum to the Peripheral and Central Nervous System Drugs Advisory Committee, contained in the FDA Briefing Document, which state the following:

1. "As the duration of exposure [to eteplirsen] in Study 202 increased, the [company] proposed comparing the clinical course of treated patients to historical controls. FDA expressed strong reservations regarding the potential interpretability of [the company's] proposed comparison to historical controls and the use of [the six minute walk test] as the primary endpoint in such a historical comparison." Proposed Third Am. Compl. ¶ 39 [#104-1] (quoting FDA Briefing Document 39 [#104-3]).

2. "FDA encouraged the [company] at the March 2013 meeting to conduct an adequately powered placebo-controlled trial of eteplirsen" and that the "FDA

further stated that, at that time, comparison data from Study 202 did not provide interpretable evidence of benefit 'given the limitations of the open-label design for protecting against bias on effort-dependent endpoints like [the six-minute walk test].'" Id. (quoting FDA Briefing Document 39 [#104-3]).

3. At the July 2013 meeting, the FDA "expressed reservations about natural history controls 'due to the usual difficulty in showing comparability between the study populations in natural history studies,' and reiterated that [the six-minute walk test] was susceptible to bias in the proposed natural history comparison." Id. (quoting FDA Briefing Document 39 [#104-3]).

4. FDA explained to the company "in detail," during a March 2013 meeting, that the modified intend-to-treat analysis for Study 202 'was unreasonable even for hypothesis generation, and why Study 201 did not provide evidence of efficacy." Id. (quoting FDA Briefing Document 38 [#104-3]).

5. FDA told Sarepta during the March 13, 2013 meeting that "while we do not believe that you have adequately characterized the quantity of truncated dystrophin produced by eteplirsen treatment (Western blot data is not available), the immunofluorescence data you presented suggest that a much lower quantity of truncated dystrophin is produced by eteplirsen treatment than is present in [Becker muscular dystrophy][1]." Id. ¶ 40 (quoting FDA Briefing Document 27 n. 5 [#104-3]).

6. "[A]s early as the July 23, 2013 meeting[,] FDA expressed concern that 'all muscle biopsies were obtained and processed by a single technician at a single study center' and that in part because of the concern about bias 'we also ask that you confirm, [biomarker results] by an independent laboratory.'" Id. (quoting FDA Briefing Document 31-32 n. 8 [#104-3]).

This court found the motion non-frivolous and not capable of being decided solely on the basis of the court's initial screening of Plaintiffs' submission. Order [#105]. Accordingly, the court allowed full briefing and a hearing on the motion. Id.

[1] The FDA Briefing Document describes Becker muscular dystrophy as "a natural model of what exon skipping in [Duchenne muscular dystrophy] might achieve. In so-called 'exon-51 model' [Becker muscular dystrophy] patients, the same truncated form of dystrophin that would be produced by eteplirsen in [Duchenne muscular dystrophy] patients occurs naturally. These [Becker muscular dystrophy] patients experience a mild, or in some cases asymptomatic muscle disease. Importantly, however, the truncated dystrophin in these [Becker muscular dystrophy] patients is expressed at high levels, roughly 50-100% of what would be expected for normal dystrophin." FDA Briefing Document 26 [#104-3].

II. Discussion

Rule 60(b)(2) permits a court to relieve a party from final judgment if evidence is newly discovered that could not have been discovered, with reasonable diligence, in time to move for a new trial under Rule 59(b). To prevail on a motion under Rule 60(b)(2), the moving party must demonstrate that (1) evidence has been discovered since the judgment; (2) the evidence could not by due diligence have been discovered earlier by the movant; (3) the evidence is not merely cumulative or impeaching; and (4) the evidence is of such a nature that it could probably change the result. Mitchell v. United States, 141 F.3d 8, 18 (1st Cir. 1998).[2] "The moving party bears the burden of establishing each of the Mitchell criteria." U.S. Steel v. DeMatteo Constr. Co., 315 F.3d 43, 52 (1st Cir. 2002).

The parties do not dispute that the FDA Briefing Document was not and could not have been discovered earlier by Plaintiffs. Defendants do, however, contend that the allegations drawn from the FDA Briefing Document are cumulative or impeaching and are not of such a nature as to probably change the result. The court agrees with Defendants that the first four portions of the FDA Briefing Document listed above are cumulative of the prior allegations, and that incorporating these allegations into the Proposed Third Amended Complaint would be futile.

As to the first portion noted above, nothing in the FDA briefing document indicates that the FDA expressed "strong reservations" about the company's proposed historical comparisons prior to July 2013. Rather, the FDA Briefing Document states that this proposal was made "as the duration of exposure to Study 202 increased," but does not specify that this occurred before

[2] Though the Mitchell standard was articulated in the context of a motion for a new trial, it has been held equally applicable to motions for relief from an order granting a motion to dismiss or for summary judgment. See, e.g., Washington v. State Street Bank & Trust Co., 14 F. App'x 12, 15 (1st Cir. 2001); U.S. Steel v. M. DeMatteo Constr. Co., 315 F.3d 43, 52 (1st Cir. 2002).

July 2013. Moreover, as alleged by Plaintiffs, the "primary efficacy endpoint" of Study 202 during the Class Period was not the six-minute walk test but was increase in truncated dystrophin in the muscle biopsies. See Proposed Third Am. Compl. ¶ 75. Accordingly, even if the FDA had expressed "strong reservations" about the use of the six-minute walk test as the "primary endpoint" in historical comparisons prior to July 2013, the company would not have been under a duty to disclose those reservations during the Class Period, when it was being used as a "secondary endpoint." Id. ¶ 76. The third portion of the FDA Briefing Document likewise suggests that the FDA "reiterated" concerns in July 2013 that the six-minute walk test was susceptible to bias in the proposed natural history comparison. Again, however, even if this concern had been stated prior to July 2013, based on Plaintiffs' allegations, it would not need to be disclosed because it did not concern the "primary endpoint" that was the basis for the anticipated NDA filing at that time.

The second cited portion of the FDA Briefing Document also fails to establish that the FDA demanded that the company to conduct a placebo-controlled trial of eteplirsen in order for an NDA to be filed, because the second portion demonstrates that need for that trial was tied to the results of the six-minute walk test, not to the results of the muscle biopsies. Moreover, to extent the results of the six-minute walk test were relevant to demonstrating the efficacy of eteplirsen—*i.e.*, to demonstrate that an increase in dystrophin correlates with clinical benefit—the company adequately disclosed weaknesses in the six-minute walk test data as the court previously concluded. See Mem. & Order 10-11 [#77]. Similarly, as to the fourth portion of the FDA Briefing Document, which states that the FDA informed Sarepta that its proposed analysis of the modified Intent-to-Treat dataset of Study 202 "was unreasonable even for hypothesis generation," this court previously concluded that Sarepta informed investors that it was using this

modified dataset. Id. Accordingly, Sarepta's failure to disclose this particular position of the FDA was not misleading, because its statements on the topic were sufficiently qualified.

In sum, the first four portions of the FDA Briefing Document highlighted by Plaintiffs do not show that the FDA expressed serious concerns or demands regarding the Sarepta's dystrophin data, or concerns about the six-minute walk test data that needed to be specifically disclosed. Accordingly, these portions of the FDA Briefing Document and Plaintiffs' new allegations based thereon do not demonstrate that Defendants' Class Period statements regarding the FDA's feedback were materially false or misleading.

The fifth and sixth portions of the FDA Briefing Document do, however, indicate that the FDA expressed serious concerns to the company regarding Sarepta's dystrophin data that were different than those previously disclosed by Defendants and were of such a nature as to require disclosure. Specifically, the fifth portion of the FDA Briefing Document indicates that, though the FDA did not agree that Sarepta's methodology for characterizing the quantity of truncated dystrophin and believed that methodology was subject to bias, see FDA Briefing Document 27-30 [#104-3], even Sarepta's data suggested that much less dystrophin was being produced by eteplirsen treatment than is present in patients with a milder form of muscular dystrophy. Similarly, the sixth portion of the FDA briefing document suggests that the FDA's concerns had not dissipated by July 2013 when the FDA specifically requested that Sarepta obtain an independent laboratory analysis of the dystrophin data that did exist.

Defendants contend that they disclosed these concerns. Specifically, Defendants point to (1) Sarepta's April 15, 2013 press release stating that the FDA had requested "a coherent and comprehensive summary to support dystrophin as a surrogate," Decl. Michael J. Vito Supp. Defs.' Mot. Dismiss Ex. 20 2 [#44-20]; (2) Sarepta's July 2013 press release stating that the

FDA had "requested additional information related to the methodology and verification of dystrophin quantification" and that "[t]he agency would not commit to declaring dystrophin an acceptable surrogate endpoint," id. Ex. 6 2 [#44-6]; and (3) Defendants' response to questions in a July 24, 2013 conference call with investors reiterating the foregoing and that "whether the production of a truncated but potentially functional dystrophin is reasonably likely to predict clinical benefit will be a review issue," id. Ex. 7 4 [#44-7].

While the foregoing disclosures reveal that the FDA was reluctant to commit to dystrophin as a surrogate for clinical benefit, they do not reveal the FDA's view that Sarepta's own analysis of its clinical data showed "a much lower quantity of truncated dystrophin data is produced by eteplirsen" than is present in Becker muscular dystrophy. Based on that portion of the FDA Briefing Document, it can be plausibly inferred that the FDA told Sarepta as of March 2013 that, even if dystrophin were accepted as a surrogate endpoint, the FDA believed that Sarepta's Phase II data did not show that eteplirsen was resulting in sufficient truncated dystrophin. These concerns are of a wholly different nature than those dystrophin-related concerns disclosed by Defendants.

In light of Defendants' statements that the FDA had given "particularly encouraging" feedback that "recognizes that our Phase IIB study data is sufficient for the FDA to consider a filing" and that the company had gotten "a yes answer to the bigger question which is an NDA filing acceptability based on the totality of our data," Proposed Am. Compl. ¶ 113, Plaintiffs have sufficiently alleged that Defendants' failure to disclose FDA's specific concerns regarding Defendants' dystrophin was misleading. See In re Cabletron Sys., Inc., 311 F.3d 11, 36 (1st Cir. 2002) ("While a company need not reveal every piece of information that affects anything said before, it must disclose facts, 'if any, that are needed so that what was revealed [before] would

not be so incomplete as to mislead.'") (quoting Backman v. Polaroid Corp., 910 F.2d 10, 16 (1st Cir. 1990) (en banc)). In addition, even statements that might otherwise be considered to be non-actionable statements of opinion were allegedly misleading and actionable in light of these new allegations. Specifically, Defendants' statement in August 2013 that "we believe we had, and still believe we have a very strong basis that the dystrophin we're producing is validating the clinical outcomes that we're seeing and should be acceptable as a surrogate end point under the accelerated approval pathway," Proposed Third Am. Compl. ¶ 113 [#104-1], and others characterizing the dystrophin data as "robust," id. ¶¶ 98, 112, fail to disclose that the FDA was allegedly taking the opposite view about the strength of Sarepta's dystrophin data. Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 135 S. Ct. 1318, 1329 (2015) (holding that, where a speaker makes a statement of belief "with knowledge that the Federal Government was taking the opposite view, the investor . . . has cause to complain: He expects not just that the issuer believes the opinion (however irrationally), but that it fairly aligns with the information in the issuer's possession at the time").

Defendants further assert that, whatever the FDA's concerns in March 2013, they were allayed by Sarepta providing, at the FDA's request, two "white papers" regarding "dystrophin methodology and verification of dystrophin quantification" in advance of the July 2013 meeting. Defendants allege that they disclosed to investors that they provided these reports. Defendants assert they therefore did not need to disclose the FDA's specific concerns, to the extent they were conveyed, that Sarepta's data showed limited quantities of dystrophin produced by eteplirsen. While it may be that these "white papers" resolved the FDA's concerns not only about the methodology for quantifying and verifying dystrophin data but also about the perceived weaknesses in the amount dystrophin produced, that issue may not be resolved on a

motion to dismiss where these facts are neither alleged in the Proposed Third Amended Complaint nor inferable from the FDA Briefing Document.

Nonetheless, though the court finds that Plaintiffs' Proposed Third Amended Complaint does now adequately allege false or misleading statements, the court concludes that filing the proposed pleading will not change the outcome, because the new evidence does not establish a sufficiently strong inference of scienter. To survive a motion to dismiss, a plaintiff in a securities action must allege an "inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 324 (2007); see also 15 U.S.C. § 78u-4(b)(2). In the First Circuit, "a plaintiff may satisfy the scienter requirement with a showing of either conscious intent to defraud or a high degree of recklessness." ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008) (quotation marks and citation omitted). In determining whether scienter is adequately alleged, the court must examine the complaint as a whole and consider "whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter." Tellabs, 551 U.S. at 322-23 ("Congress did not merely require plaintiffs to provide a factual basis for their scienter allegations . . . . Instead, Congress required plaintiffs to plead with particularity facts that give rise to a 'strong'—*i.e.*, a powerful or cogent—inference.") (quotation marks and citation omitted). Because "[t]he strength of an inference cannot be decided in a vacuum. . . . a court must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." Id. at 323-24.

Here, considering all the facts alleged, the court cannot find that Plaintiffs have established as strong of an inference of an intent to deceive (or of recklessness) as the competing inference that Defendants were merely negligent in failing to disclose the FDA's specific

concerns. This is because, though Defendants failed to disclose material information regarding the FDA's view on the dystrophin data, they did substantially disclose the FDA's hesitation to commit to dystrophin as an acceptable surrogate endpoint and the limitations of the Phase IIb data generally. See Fire and Police Pension Ass'n of Colorado v. Abiomed, Inc., 778 F.3d 228, 243 (1st Cir. 2015) ("Abiomed's substantial disclosures about its correspondence with the FDA. . . . undercut any inference of scienter."); ACA Fin. Guaranty Corp., 512 F.3d at 66 (the inference that defendants acted with scienter was not equally as strong as competing inferences in part because "the Official Statement as a whole candidly laid out the sorry financial history of the college"). Thus, rather than supporting an inference of intentional deception or recklessness, the allegations suggest that Defendants actually sought to inform the public of the FDA's concerns but failed to adequately do so.

Moreover, while Plaintiffs allege that the company was making an "At the Market" offering in July 2013 to raise capital, and thus suggest that Defendants had a motive to deceive the market, Proposed Third Am. Compl. ¶¶ 184-185, "catch-all allegations that defendants stood to benefit from wrongdoing and had the opportunity to implement a fraudulent scheme are not sufficient." Greebel v. FTP Software, Inc., 194 F.3d 185, 197 (1st Cir. 1999) (citation omitted). Plaintiffs must support these allegations with further allegations of "some additional misconduct," and no such misconduct is alleged here. See In re Smith & Wesson Holding Corp. Sec. Litig., 604 F. Supp. 2d 332, 344 (D. Mass. 2009); see also Cozzarelli v. Inspire Pharms., Inc., 549 F.3d 618, 627 (4th Cir. 2008) ("If we inferred scienter from every bullish statement by a pharmaceutical company that was trying to raise funds, we would choke off the lifeblood of innovation in medicine by fueling frivolous litigation—exactly what Congress sought to avoid by enacting the PSLRA.") In addition, there are no allegations of sales by high-level insiders during

the class period, and indeed, public records reveal that Sarepta's CFO purchased 5,000 shares in August 2013, during the Class Period. See Decl. Michael J. Vito Supp. Defs.' Mot. Dismiss Ex. 27 2 [#44-27]; see also Guerra v. Teradyne, Inc., 01-11789-NG, 2004 WL 1467065, at *28 (D. Mass. Jan. 16, 2004) (lack of sales by high-level insiders weighs against a finding of scienter).

To be clear, the court's conclusion that the FDA had communicated its specific and substantial concerns to Defendants about what their dystrophin data showed supports an inference that Defendants were aware that the FDA's opinion strongly contrasted with their own positive outlook. Absent the additional facts here showing that Defendants were careful not to overstate the FDA's acceptance of the data they did have, and belying any allegation of misconduct, this might be enough. On these facts, however, the inference of a non-culpable state of mind is stronger than the one necessary to survive a motion to dismiss.

Accordingly, filing the Proposed Third Amended Complaint would be futile, and Plaintiffs' Motion for Relief from Judgment Pursuant to Fed. R. Civ. P. 60(b)(2) [#103] is DENIED.

IT IS SO ORDERED.

Date: April 21, 2016

/s/ Indira Talwani
United States District Judge